JC02 Rec'd PCT/PTO 25 MAR 2002

FORM PTO-1390 (Modified) (REV 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: **TRUF101**

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5): 10/089262

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/IT00/00424	**20 OCTOBER 2000**	**21 OCTOBER 1999**

TITLE OF INVENTION

GASTRORESISTANT TABLETS FOR ALIMENTARY, DIETETIC AND THERAPEUTIC USE

APPLICANT(S) FOR DO/EO/US

SENECI, Alessandro AND ALBERICO, Pia

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include itens (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☒ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

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U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/089262	PCT/IT00/00424	TRUF101

24. The following fees are submitted:.

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

		CALCULATIONS PTO USE ONLY
☐	Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**	
☒	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**	
☐	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**	
☐	International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**	
☐	International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**	
	ENTER APPROPRIATE BASIC FEE AMOUNT =	**$890.00**
	Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	**$0.00**

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	13 - 20 =	0	x $18.00	**$0.00**
Independent claims	1 - 3 =	0	x $84.00	**$0.00**
Multiple Dependent Claims (**check if applicable**).			☒	**$280.00**
	TOTAL OF ABOVE CALCULATIONS =			**$1,170.00**
☒	Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.			**$585.00**
	SUBTOTAL =			**$585.00**
	Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +			**$0.00**
	TOTAL NATIONAL FEE =			**$585.00**
☒	Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (**check if applicable**).			**$40.00**
	TOTAL FEES ENCLOSED =			**$625.00**
				Amount to be: refunded $
				charged $

a. ☒ A check in the amount of **$625.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☐ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _____ A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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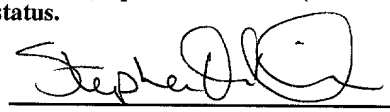

SIGNATURE

STEPHEN M. NIPPER
NAME

46,260
REGISTRATION NUMBER

03-25-2002
DATE

Gastroresistant tablets for alimentary, dietetic and therapeutic use

The present invention relates to gastro-resistant formulations, preferably tablets, for alimentary or dietary use, which are obtained by mixing the composition with fat in order to achieve a prolonged release of the active principles contained therein to the organism.

The preparation of the gastro-resistant formulations is usually carried out so as to allow the active principle to be released and absorbed in a more or less retarded manner at the intestine level; alternatively, the active principle may be released and absorbed only in part at the stomach level, thus allowing a second fraction of the active principle to be released and absorbed at the intestine level.

The known technique for preparing gastro-resistant formulations with retarded release is as follows:

A) Gastro-resistant formulations: these are tablets lined with gastro-resistant films, such as, for example, ethylcellulose, cellulose acetophthalate, polyacrylates, gum lac, keratine; the lined tablets are then coated with sugar.

B) Layered formulations: they are prepared in the same manner as the gastro-resistant sugar-coated pills, with regard to coating of the tablets; a sprinkling powder such as starch or talcum, in which an active principle is dispersed using a water-soluble product such as gum arabic, agar-agar etc. as the adhesive, is attached layerwise to the coated core, in such a manner that the outermost layer and not the inner tablet is dissolved in the stomach.

C) Capsules containing retarding agents; they are sugar cores in which the active principle is dispersed, followed by application of a protective coating as in para. A);

D) Tablets in which retarding agents are dispersed in such a way that part of the active principle is present in the gastro-resistant retarding agents and part is present in the water-dispersible tablet;

E) Multi-layered tablets in which one or more layers contain dissolution-retarding powders, such as cellulose-derived gum lacs so that the layers have different solubilities.

In general, they are formulations whose retarding effect is based on the use of excipients and/or adjuvants foreign to the mammalian organism, in particular of humans, which formulations are intended to maximize the absorption of the active

principle without taking into consideration the normal physiological digestive processes.

However, the use of such substances is usually not very desirable, in particular in the case of dietary formulations and/or in the case of food additives which are intended to achieve instead an absorption of the active principle according to a kinetic profile which is as close as possible to the normal human digestive processes.

The recourse to "natural" absorption profiles is anyway desirable, even in the case of therapeutic formulations, for example in all those classes of patients who would be harmed by administering them non-"physiological" excipients and/or adjuvants; obvious examples are pregnant women, very young children, allergic subjects, etc.

Now, according to the subject-matter of the present invention, a novel fomulation with retarded release has been found, said formulation allowing the active principles to be absorbed utilizing the physiological digestive activity, i.e. imitating what happens with food ingested in the usual manner.

The present invention relates to a formulation in tablet form for oral use, containing at least one active principle with a pharmaceutical, dietary or alimentary action in combination with at least one fat and/or phospholipid, as the vehicle, in an amount of between 5 und 30%, relative to the weight of the formulation; preferably, such fats and/or phospholipids are present in an amount of between 20 and 30%, relative to the weight of the formulation.

The fatty acids contained in the fats and phospholipids which can be used for the purposes of the present invention are normally selected from those containing hydrogenated and non-hydrogenated fatty acids, either of synthetic or natural origin, having a chain comprising between 3 and 20 carbon atoms, preferably between 14 and 18 carbon atoms, and mixtures thereof.

A non-limiting list of such acids comprises, for example, palmitic acid, stearic acid, myristic acid, lauric acid, caprylic acid, capric acid, etc.

From a practical point of view, the fats can normally be selected from among cocoa butter, hydrogenated palm oil, hydrogenated vegetable fats such as peanut butter, animal fats such as lard, butter, bacon fat separately or in a mixture thereof.

The phospholipids are instead preferably used as lecithins and, in particular, as soya lecithin. If desired, the abovementioned fats and phospholipids may also be

used in combination with alkali metal salts and/or alkaline earth metal salts of fatty acids having a chain comprising between 3 and 20 carbon atoms, preferably between 14 and 18 carbon atoms, or mixtures thereof, the preferred salts being those of sodium, potassium and calcium.

As indicated above, the active principles which can be used for the purposes of the present invention may have both a therapeutic and a dietary or alimentary action. The active principles with a therapeutic action may be selected from among non-steroid anti-inflammatory drugs (NSAID) and steroid anti-inflammatory drugs, tranquilizers, sleeping pills, anti-hypertensive, anti-histaminic and anti-asthmatic drugs; non-steroid anti-inflammatory drugs in turn may be selected from among ibuprofen, naproxen, ketoprofen, indomethacin, acetylsalicylic acid, mefenamic acid, flufenamic acid, etc.; the active principles with a dietary action may be selected from the group consisting of lactic acid microorganisms, beer yeasts, either as such or containing living cells, vitamins, minerals, amino acids, vegetable extracts, and derivatives thereof.

In the formulation according to the present invention, the active principle or principles, which may be used as such or in the form of esters or physiologically acceptable salts, can be mixed directly with said at least one fat and/or phospholipid without the addition of any excipients and/or adjuvants; in this case, the active principle or principles make up 70-95% by weight, preferably 75-90% by weight, of the formulation.

Alternatively, the abovementioned active principles may be used in combination with customary excipients and/or adjuvants known in the art; in this case, they are normally present in amounts of between 1 and 50%, preferably between 10 and 40%, relative to the total weight of the formulation.

The excipients used for the tablet accordintg to the present invention may be selected from the group consisting of starches, maltodextrin, microcrystalline cellulose, talcum-modified cellulose, calcium carbonate, milk proteins, calcium stearate, magnesium stearate, sodium stearate, soya proteins or suitable inert powders, PVP, precipitated silica and are present in an amount of 10-30% by weight, preferably 20-30% by weight, relative to the total weight of the formulation.

In order to determine the release activity, over time, of an active principle contained in a formulation according to the present invention (the qualitative and quantitative composition of which is given in Example 1), the dissolution test described in Farmacopea Ufficiale Italiana (Official Italian Pharmacopeia) was carried out. The results of said test are shown in the table below.

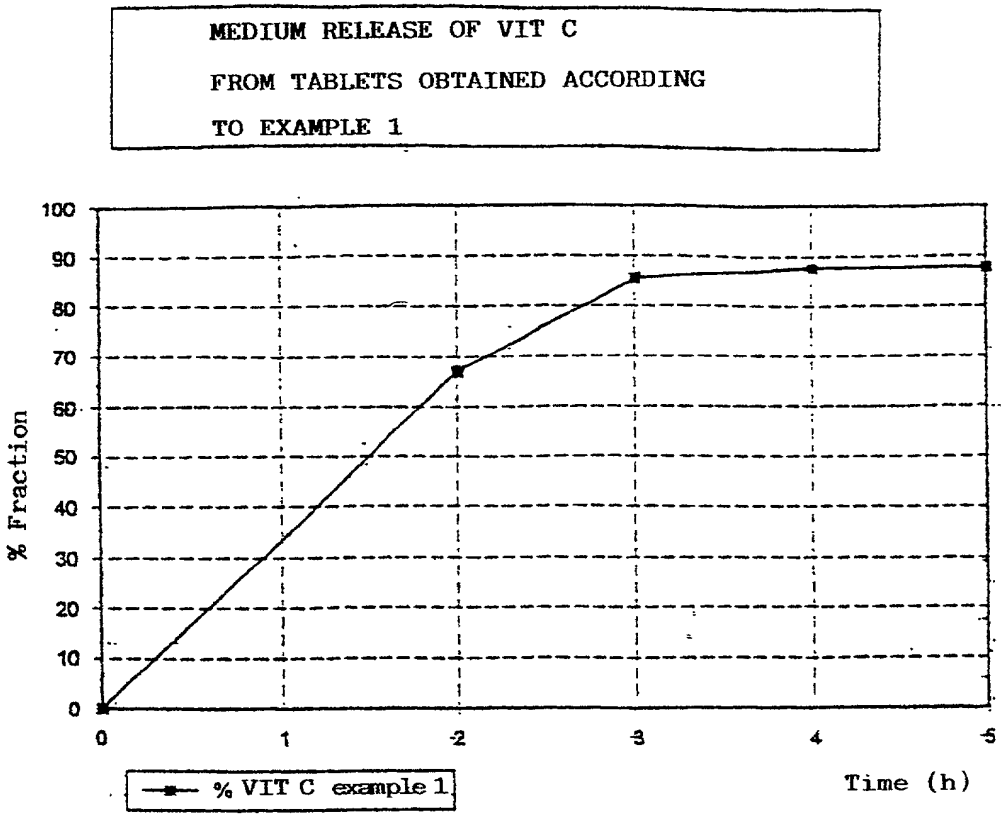

TABLE I

This dissolution test demonstrates the slow release, over time, of an active principle under physiological conditions which simulate the digestive processes which normally take place in the stomach.

The present invention is particularly suitable for the production of BIO-certified gastro-resistant tablets, provided that fats derived from biological cultivations and farms in accordance with current regulations are used.

The present invention furthermore relates to the process for the preparation of the formulations according to the present invention.

Said process comprises premixing an active principle as defined above in an amount of 1-50% by weight, relative to the total weight of the formulation, with the excipients as defined above, which in turn are present in an amount of 10-30%, relative to the total weight of the formulation. The mixture thus obtained by simple mixing at ambient temperature or by dry or wet granulation in accordance with the known technique is kneaded in a suitable kneader, usually a Z-type kneader or plunging-arm kneader, together with at least one fat and/or phospholipid in the melted state in an amount of between 5 and 30%, relative to the weight of the formulation.

The blend thus obtained is cooled to 5-20° C, preferably to 10°C-12° C, and then granulated, for example using an oscillating granulator of the Manesty type equipped with a perforated stainless steel plate having holes with a diameter of 1-4 mm, preferably 1-2 mm.

The granules thus obtained are compressed with a rotary tablet-compressing machine equipped with suitable punches. It is thus possible to obtain tablets of suitable weight.

In the case of tablets not containing added excipients and/or adjuvants, the active principle is mixed directly with the fat and/or phospholipid in the melted state; the mixture is then processed as described above.

In particular, the present invention is highly suitable for the preparation of layered tablets obtained with a suitable tablet-compressing machine such as, for example, a Manesty BB3B.

The process consists in compressing a layer obtained according to the prior art using one or more active principles mixed with known water-soluble or water-dispersible excipients and one layer obtained according to the present invention. If

desired, it is also possible to use more than two layers with different degrees of solubility.

The examples which follow are given in order to describe better the present invention without, however, limiting its scope.

Example 1

1000 tablets are prepared, being formed by a fast-dissolving layer (Layer A) obtained by kneading, in a Z-type kneader, the following components together with 10% strength Klucel/water:

proline (100 g),

lysine (100 g),

cystine (100 g),

sodium carboxymethylcellulose (20 g)

The blend thus obtained is dried for 12 hours at 40°C in a drying cabinet, the resulting mixture is granulated in a Manesty granulator equipped with a perforated stainless steel plate having holes with a 2-mm diameter, giving a yield of 321.8 g.

The granules thus obtained are mixed in a rotating-screw mixer (SAGA) with :

red lake N° 40 all lake (0.25 g),

vitamin A 5,000,000 IU/g (800 µg/cpr +30%) (2.31 g),

vitamin E 50% SD (16 mg/cpr +20%) (12.8 g),

vitamin C granules (49.5 g),

magnesium stearate (5 g),

copper gluconate Cu 14% (1.2 mg/cpr + 5%) (6 g),

zinc gluconate Zn 13.4% (10 mg/cpr + 5%) (52.2 g)

selenium-containing yeast 2,000 µg/g (0.055 µg/cpr + 5%) (19 g)

glutathione on yeast (25 mg/cpr + 20%) (15 g),

rapidly disintegrating PVP (20 g),

potato starch (10 g),

silica gel (3 g),

maltodextrin (5 g),

microcrystalline cellulose (2 g),

water (0.5 g),

giving a total yield of 524.36 g.

A second mixture is prepared and used to form the slow-dissolving layer (LAYER B) thus obtained:

lyophilized blueberry (15 g),

microcrystalline cellulose (50 g),

titanium dioxide (10 g),

nucleic acids (50 g),

blueberry extract 25% (50 g),

copper gluconate (1.5 g),

zinc gluconate (12.3 g),

copper gluconate (1.5 g),

zinc gluconate (13.8 g),

selenium-containing yeast (9.5 g),

glutathione on yeast (15 g),

vitamin A 500,000 IU/g (4.63 g),

vitamin E 50% SD (25.6 g),

vitamin C EC 97% (99 g),

All these components are mixed and kneaded in a Z-type kneader together with melted hydrogenated palm oil (50 g).

The blend obtained is cooled to 12°C and granulated in an oscillating granulator equipped with a stainless steel plate having holes with a 2 mm diameter, giving a total yield of 408 g.

The two mixtures thus obtained can be compressed with an oval punch using a double-layered tablet-compressing machine (MANESTY BB3B) producing oval tablets with a weight of 0.932 g, in which the first layer weighing 0.524 g is fast-dissolving and the second layer weighing 0.408 g is gastro-resistant and slow-dissolving.

Example 2

Example 1 is repeated, except that the following components are used:

Layer A (FAST-DISSOLVING)

folic acid 98% (0.3 mg/cpr + 20%) (0.12 g)

vitamin B6 33.1/3 (1.5 mg + 20%) (1.8 g)

beta carotene 20% (4mg/cpr + 10%) (7.4 g)

vitamin E 50% SD (116 mg/cpr) (12.8 g)

vitamin C EC 97 (120 mg/cpr +20%) (49.5 g)

copper gluconate Cu 14% (1.2 mg/cpr) (6 g)

zinc gluconate Zn 13.4% (10 mg/cpr) (52.3 g)

selenium-containing yeast 2000 µg/g (55 µg/cpr) (19.3 g)

lactose CD (150 g)

microcrystalline cellulose (30 g)

water (4 g)

potato starch (30 g)

rapidly disintegrating PVP (Kollidon CL) (10 g)

silicagel (10 g)

maltodextrin (8g)giving a total of 391.22 g:

Layer B (SLOW-DISSOLVING)

sulfomucopolysaccharides (25 g)

Gingko biloba (30 g)

copper gluconate Cu 14% (3 g)

zinc gluconate Zn 13.4% (26.2 g)

selenium-containing yeast 2,000 µg/g (9.7 g)

microcrystalline cellulose (50 g)

red iron oxide (5 g)

folic acid (0.24 g)

vitamin B6 33.1/3% (3.6 g)

vitamin E 50% (25.6 g)

vitamin C EC 97% (99 g)

beta carotene 20% (14.8 g)

melted hydrogenated palm oil (72 g)

silica gel (0.5%),

giving a total of 0.358 g.

Double-layered tablets weighing 0.749 g are prepared, the first layer of which weighing 0.391 g is fast-dissolving and the second one weighing 0.358 g is slow-dissolving.

The tablets can then be coated with a solution of

10 % strength Klucel/water.

Example 3

Example 1 is repeated, except that the following components are used:

Layer A (FAST-DISSOLVING)	
acetylsalicylic acid	0.3 g
hydrogenated palm oil	0.1 g
lactose	0.2 g
Layer B (SLOW-DISSOLVING)	
acetylsalicylic acid	0.2 g
lactose	0.1 g
magnesium stearate	0.01 g
pre-dried corn starch	0.1 g

the sum of the components (a), (b) and (c) making up 100% by weight of the formulation.

8. Formulation according to Claim 7, characterized in that said excipients are selected from among starches, maltodextrin, microcrystalline cellulose, talcum-modified cellulose, calcium carbonate, milk proteins, calcium stearate, magnesium stearate, sodium stearate, soya proteins or suitable inert powders, PVP, and precipitated silica.

9. Process for the preparation of a formulation according to Claim 5 in which:

a) said at least one active principle is mixed with said at least one fat and/or phospholipid in the melted state in the weight proportions defined above;

b) the blend thus obtained is cooled to 5-20°C, preferably to 10°C-12°C, and then granulated using a granulator having holes with a diameter of between 1 and 4 mm, preferably between 1 and 2 mm;

c) the granules thus obtained are then compressed.

10. Process for the preparation of a formulation according to Claim 7 in which:

d) said at least one active principle is premixed at ambient temperature with said excipients and/or adjuvants in the weight proportions defined above;

e) the mixture thus obtained is mixed with said at least one fat and/or phospholipid in the melted state in the weight proportions defined above;

f) the blend thus obtained is cooled to 5-20°C, preferably to 10°C-12°C, and then granulated using a granulator having holes with a diameter of between 1 and 4 mm, preferably between 1 and 2 mm;

g) the granules thus obtained are then compressed.

CLAIMS

1. Process for the preparation of a retarded release formulation for oral use in tablet form, containing at least one active principle with a pharmaceutical, dietary or alimentary action and at least one hydrogenated fatty acid, as the vehicle, in amounts of between 5 and 30%, relative to the weight of the formulation, wherein:

(a) said at least one active principle is mixed with said at least one hydrogenated fatty acid in the melted state in the weight proportions defined above;

(b) the blend thus obtained is cooled to 5-20°C and then granulated using a granulator having holes with a diameter of between 1 and 4 mm;

(c) the granules thus obtained are then compressed.

2. The process according to claim 1, wherein said hydrogenated fatty acid is present in amounts between 10 and 20%, relative to the weight of the formulation.

3. The process according to claim 1, wherein the blend in point (b) is cooled to 10°C-12°C.

4. The process according to claim 1, wherein the blend in point (b) is granulated using a granulator having holes with a diameter of between 1 and 2 mm.

5. The process according to claim 1 wherein:

(d) said at least one active principle is premixed at ambient temperature with said excipients and/or adjuvants in the weight proportions defined above;

(e) the mixture thus obtained is mixed with said at least one fat and/or phospholipid in the melted state in the weight proportions defined above;

(f) the blend thus obtained is cooled to 5-20°C, preferably to 10°C-12°C, and then granulated using a granulator having holes with a diameter of between 1 and 4 mm, preferably between 1 and 2 mm;

(g) the granules thus obtained are then compressed.

6. A formulation obtainable by the process according to claims 1-5.

7. A formulation according to claim 6, characterized in that said at least one hydrogenated fatty acid has a chain comprising between 3 and 20 carbon atoms, preferably between 14 and 18 carbon atoms, or mixtures thereof.

8. A formulation according to claim 6, characterized in that said at least one hydrogenated fatty acid is hydrogenated palm oil.

9. A formulation according to claim 6, characterized in that said at least one active principle is present in an amount of 70-95%, preferably 75-90%, relative to the weight of the formulation, and in that said at least one active principle and said at least one hydrogenated fatty acid make up 100% by weight of the formulation.

10. A formulation according to claim 6, characterized by containing: (a) from 10 to 50% by weight, of at least one active principle with a pharmaceutical, dietary or alimentary action; (b) from 5 to 30% by weight of at least one fat and (c) exicipients and/or adjuvants, the sum of the components (a), (b) and (c) making up 100% by weight of the formulation.

11. A formulation according to claim 10, characterized by containing from 30 to 50% by weight of component (a).

12. A formulation according to claim 10, characterized by containing from 20 to 30% by weight of component (b).

13. A formulation according to claim 6, characterized in that said at least one active principle with a therapeutic action is selected from non-steroid and steroid anti-inflammatory drugs, tranquilizers, sleeping pills, anti-hypertensive, anti-histaminic and anti-asthmatic drugs and in that said at least one active principle with a dietary or alimentary action is selected from the group consisting of lactic acid microorganisms, beer yeasts, either as such or containing living cells, vitamins, minerals, amino acids, vegetable extracts, and derivatives thereof.

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WO 01/28526 A3

(54) Title: GASTRORESISTANT TABLETS FOR ALIMENTARY, DIETETIC AND THERAPEUTIC USE

(57) Abstract: A novel formulation for oral use is described, said formulation containing at least one active principle with a pharmaceutical, dietary or alimentary action, in combination with at least one fat and/or phospholipid in an amount of between 5 and 30 %, relative to the weight of the formulation; this formulation allows the slow release, over time, of the active principle under physiological conditions which simulate the digestive processes which normally take place in the stomach.

PTO/SB/104 (8-96)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Declaration and Power of Attorney for Patent Application

Dichiarazione e procura ai fini della domanda di brevetto

Italian Language Declaration

Il sottoscritto inventore dichiara che:

As a below named inventor, I hereby declare that:

La propria residenza, recapito postale e cittadinanza corrispondono a quanto indicato in calce, sotto la propria firma.

My residence, post office address and citizenship are as stated next to my name.

ALESSANDRO SENECI and PIA ALBERICO

Ritiene di essere il primo ed unico inventore originale (se viene elencato in calce un solo nominativo) o il coinventore primo ed originale (se è elencato più di un nominativo) del oggetto rivendicato e per il quale il sottoscritto presenta domanda di brevetto. La invenzione in questione è chiamata

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

GASTRORESISTANT TABLETS FOR ALIMENTARY, DIETETIC AND THERAPEUTIC USE

e la sua descrizione è allegata alla presente Dichiarazione a meno che non sia spuntata la seguente casella:

the specification of which is attached hereto unless the following box is checked:

☐ Il _____ è stata depositata una domanda di brevetto statunitense numero o una domanda di brevetto internazionale PCT numero _____ che è stata modificata il _____ (se applicabile).

☐ was filed on _____ as United States Application Number or PCT International Application No. PCT/IT00/00424 and was amended on _____ (if applicable).

Il sottoscritto dichiara in oltre di aver letto e compreso il contenuto della descrizione identificata in precedenza, rivendicazioni comprese, come modificati dall'eventuale modifica summenzionata.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

Il sottoscritto riconosce l'obbligo di rivelare informazioni essenziali ai fini della determinazione della brevettabilità ai sensi del Titolo 37, Codice dei Regolamenti Federali, § 1.56.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

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Il sottoscritto rivendica con la presente la priorità prevista dal Titolo 35, Codice degli Stati Uniti, § 119(e)-(d) o § 365(b) in relazione a qualsiasi domanda o domande estere di brevetto o certificato di inventore, o dal Titolo 35, § 365(a) degli stessi Codice in relazione a qualsiasi domanda internazionale PCT nella quale è designato almeno un paese diverso dagli Stati Uniti, i suddetti domande e certifcati essendo elencati sotto, e, spuntando les seguenti caselle, ha anche identificato sotto qualsiasi domanda estera di brevetto o certificato di inventore, o domanda internazionale PCT, la cui data di deposito preceda quella della domanda per la quale è rivendicata la priorità.

I hereby claim foreign priority under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Aplication(s)
Domande Estere Anteriori

Priority Not Claimed
Diritto di priorità non rivendicato

(Number) (Numero)	(Country) (Nazione)	(Day/Month/Year Filed) (Giorno/Mese/Anno di deposito)	
MI99A002206	ITALY	21 OCTOBER 1999	☐
			☐

Il sottoscritto rivendica con la presente i benefici previsti dal Titolo 35, Codici degli Stati Uniti, § 119(e), in relazione a qualsiasi domanda o domande provvisorie degli Stati Uniti elencate sotto.

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below.

(Application No.) (N° della domanda)	(Filing Date) (Data di deposito)

Il sottoscritto rivendica con la presente i benefici previsti dal Titolo 35, Codice degli Stati Uniti, § 120, in relazione a qualsiasi domanda o domande statunitensi, o dal Titolo 35, § 365(c) degli stessi Codice in relazione a qualsiasi domanda internazionale PCT nella quale sono designati gli Stati Uniti, i suddette domande essendo elencate sotto e, nella misura in cui l'oggetto di ciascuna rivendicazione di questa domanda non sia stato esposto nella domanda statunitense o internazionale PCT anteriore nel modo previsto dal primo paragrafo del Titolo 35, Codice degli Stati Uniti, § 112, riconosce l'obbligo di rivelare informazioni essenziali ai fini della determinazione della brevettabilità ai sensi del Titolo 37, Codici dei Regolamenti Federali, § 1.56, le quali diventino disponibili durante il periodo compreso tra la data di deposito della domanda anteriore e la data di deposito nazionale o internazionale PCT della presente domanda.

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

(Application No.) (N° della domanda)	(Filing Date) (Data di deposito)	(Status) (patented, pending, abandoned) (Stato) (concessione di brevetto, in corso di esame, abbandono)
PCT/IT00/00424	October 20, 2000	

Con la presente, il sottoscritto dichiara veritiere tutte le affermazioni contenute in questa domanda in relazione alle proprie conoscenze e di ritenere vere tutte le affermazioni o informazioni presentate. Dichiara inoltre che tali asserzioni sono state espresse nella piena consapevolezza che le dichiarazioni intenzionalmente false sono punibili con una multa, l'incarcerazione o entrambe, ai sensi della Sezione 1001 del Titolo 18 del Codice degli Stati Uniti e che tali dichiarazioni intenzionalmente false possono mettere a repentaglio la validità della domanda o di qualsiasi brevetto rilasciato in merito.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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PROCURA: Il sottoscritto inventore nomina con la presente il seguenie avvocato o avvocati e/o agente o agenti al fine di istruire questa pratica e di condurre tutte le operazione ad essa pertinenti presso l'Ufficio dei Brevetti e Marchi di Fabbrica: *(Elencare il nome ed il numero di matricola).*

Inviare le corrispondenza a:

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: *(list name and registration number).*

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(Fornire le stesse informazioni e le firme del terzo e degli ulteriori coinventori.)

(Supply similar information and signature for third and subsequent joint inventors.)